

In re: S. Gupta et al.
Serial. No.: 10/010,914
Filed: December 5, 2001
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In the claims:

Please cancel and amend the claims as indicated below:

A1
1 (canceled).

2 (canceled).

3 (canceled).

4 (canceled).

5 (canceled).

6 (canceled).

7 (canceled).

8 (canceled).

9 (canceled).

10 (canceled).

11 (original). A pharmaceutical emulsion composition for parenteral delivery, said composition comprising, in combination:

(a) a hydrophilic phase;

(b) from 2 to 40 percent volume per volume of a pharmacologically acceptable lipid as a hydrophobic phase dispersed as particles in said hydrophilic phase;

(c) from 0.01 to 2 percent weight per volume of a retinide;

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cont'd

- (d) from 0 to 10 percent volume per volume of a solvent;
- (e) from 0.01 to 10 percent weight per volume of a non-ionic surfactant to stabilize said emulsion composition; and
- (f) from 0 to 10 percent weight per volume of an isotonic agent; said emulsion composition having a pH of about 5 to 10.

12 (original). The composition of claim 11 wherein said retinide is fenretinide.

13 (original). The composition of claim 12 wherein fenretinide is present at about 0.1 to 0.5 percent weight per volume.

14 (original). The composition of claim 11 wherein the solvent is present in an amount of at least 0.01 percent volume per volume and is selected from the group consisting of ethanol, dimethylsulfoxamide (DMSO), and ethyl acetamide (DMA).

15 (original). The composition of claim 14 wherein the solvent is ethanol at about 0.01 to 5.0 percent volume per volume.

16 (original). The composition of claim 11 wherein the lipoid is selected from the group consisting of soybean oil, safflower oil, sunflower oil, borage oil, corn oil, olive oil, linseed oil, sesame oil, palm kernel oil, cotton seed oil, medium chain triglycerides from coconut oil distillates, black currant oil, and mixtures thereof.

17 (original). The composition of claim 16 wherein said lipoid is soybean oil at 10 to 30 percent volume per volume.

18 (currently amended). The composition of claim 11 wherein the non-ionic surfactant is selected from the group consisting of egg phospholipids, polyoxyethylene fatty acid esters, or a and block copolymers of polyoxypropylene and polyoxyethylene.

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19 (original). The composition of claim 18 wherein the non-ionic surfactant is egg phospholipid at about 2 percent weight per volume.

20 (original). The composition of claim 11 wherein the isotonic agent is present in an amount of about 1 to 3 percent weight per volume.

21 (original). The composition of claim 20 wherein the isotonic agent is glycerin at about 1 per cent weight per volume.

22 (original). The composition of claim 11 wherein the amount of retinide is about 0.1 to 0.5 percent weight per volume, the solvent is dehydrated ethanol at 0.0 to 5.0 percent volume per volume, the amount of said lipoid is about 10 to 30 percent volume per volume, the amount of egg phospholipids is about 1 to 5 percent weight per volume, the isotonic agent is glycerin at about 1 percent weight per volume, and the pH is from 5.0 – 10.0.

23 (original). The composition of claim 1 wherein said particles are from 5 to 1000 nanometers in diameter.

24 (original). The composition of claim 23 wherein said particles are from 50 to 400 nanometers in diameter.

25 (original). A method of treating a hyperproliferative disorder in a subject in need thereof, comprising parenterally administering to said subject a composition according to claim 11 in an amount effective to treat said hyperproliferative disorder.

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26 (original). The method of claim 25, further comprising the step of diluting said composition in an aqueous pharmaceutically acceptable carrier prior to said administering step.

27 (original). The method of claim 25, wherein said administering step is an intravenous administration step.

28 (original). The method of claim 25, wherein said subject is a human subject.
